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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,451	12/30/2003	Michael J. Bonnette	POSSIS P541	2401
21270	7590	05/19/2008	EXAMINER	
HUGH D JAEGER, P.A.			NEAL, TIMOTHY J	
P.O. BOX 672			ART UNIT	
WAYZATA, MN 55391-0672			PAPER NUMBER	
			3731	
			MAIL DATE	
			DELIVERY MODE	
			05/19/2008	
			PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



## DETAILED ACTION

This action is in response to the Request for Continued Examination received on 02/22/2008.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1, 9, 12-14, and 16** are rejected under 35 U.S.C. 102(e) as being anticipated by Douk et al. (2002/0151927).

1. Apparatus for use in vascular procedures comprising: a. a tubular guidewire (20) having a proximal end, a distal ends, and a lumen; b. a control cable (42) having a proximal end and a distal end disposed in the lumen of the tubular guidewire; and, c. a sheathless filter (25) distally coupled to the control cable and proximally coupled to the tubular guidewire, the sheathless filter being radially expandable in response to displacement of the control cable relative to the tubular guidewire such that the sheathless filter presents at least a convex primary filter surface to a flow of blood within

a blood vessel when introduced thereinto and expanded (see paragraphs 17 and 18).

9. The apparatus of claim 1, wherein the sheathless filter comprises a tubular braided wire framework; and, a filter mesh formed of nitinol wires co-braided with the wires of the tubular braided wire framework (Figure 5, select at least two wires that intersect each other and that is the tubular braided wire framework, the remaining wires are considered the filter mesh).

12. The apparatus of claim 1, wherein the sheathless filter includes means for visibly identifying the sheathless filter under fluoroscopy (Paragraph 51).

13. The apparatus of claim 1, wherein the sheathless filter includes a distal interior face presenting a concave secondary filter surface to the flow of blood within the blood vessel (Fig 5).

14. The apparatus of claim 1, wherein the proximal end of the tubular guidewire is free of mechanical connections and obstructions so as to enable the tubular guidewire to function as a conventional exchange guidewire while the sheathless filter is deployed (No mechanical connections disclosed, guidewire is disclosed as functioning like a conventional guidewire).

16. The apparatus of claim 1, wherein the sheathless filter is formed of resilient flexible

members interlaced to form a tubular net (25), the tubular net having an undeployed state in which the flexible members lie generally parallel to a longitudinal axis of the control cable and tubular guidewire and having a plurality of selectively deployable states in which the flexible members are radially expanded from the longitudinal axis of the control cable and tubular guidewire to a diameter coincident with a diameter of the blood vessel (Fig 5 and paragraphs 17 and 18).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 2-5 and 15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Douk et al. (2002/0151927).

Douk discloses the invention substantially as claimed as stated above. Douk does not explicitly disclose a means for resisting displacement of the control cable in the specific embodiment referenced by the Examiner. Douk does disclose a stop element in some of the embodiments to limit axial movement (Paragraph 19). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Douk's filter assembly to include a resisting means to prevent overexpansion of the filter. Also, the Applicant has provided no advantage to the three claimed embodiments of the resisting means. Therefore, it would have been

obvious to a person having ordinary skill in the art to interchange a tube, a clamp, and a stop.

Douk does not explicitly disclose the outer diameter of the filter. However, it is well known and within the purview of one having ordinary skill in the art to modify the size of filters to fit specific anatomical features. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Douk's filter to have a maximum outer diameter as claimed. Such a modification would prevent a filter that is too large for the desired vessel from damaging the vessel upon expansion.

**Claims 2-5** are rejected under 35 U.S.C. 103(a) as being unpatentable over Douk et al. (2002/0151927) in view of Kusleika et al. (US 6,325,815).

Douk discloses the invention substantially as claimed as stated above. Douk does not explicitly disclose a means for resisting displacement of the control cable. Kusleika teaches the use of a stop (40) to prevent overexpansion of the filter. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Douk's filter assembly to include Kusleika's resisting means. Such a modification would prevent overexpansion of the filter. Also, the Applicant has provided no advantage to the three claimed embodiments of the resisting means. Therefore, it would have been obvious to a person having ordinary skill in the art to interchange a tube, a clamp, and a stop.

**Claims 2-5** are rejected under 35 U.S.C. 103(a) as being unpatentable over Douk et al. (2002/0151927) in view of Seguin et al. (US 6,562,058).

Douk discloses the invention substantially as claimed as stated above. Douk does not explicitly disclose a means for resisting displacement of the control cable. Seguin teaches a clamp device for controlling the movement of an actuating cable (Figs 8A-D). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Douk's filter assembly to include Seguin's resisting means. Such a modification would prevent overexpansion of the filter. Also, the Applicant has provided no advantage to the three claimed embodiments of the resisting means. Therefore, it would have been obvious to a person having ordinary skill in the art to interchange a tube, a clamp, and a stop.

**Claims 6-8, 10, and 11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Douk et al. (2002/0151927) in view of Greenhalgh (US 6,364,895).

Douk discloses the invention substantially as claimed as stated above. Douk also discloses a tubular braided wire framework (25); wherein the tubular braided wire framework is constructed of biocompatible nitinol wire (Paragraph 44); wherein a distal end of the tubular braided wire framework is operably attached to the control cable and a proximal end of the tubular braided wire framework is operably attached to the tubular guidewire (Paragraphs 17 and 18). Douk does not explicitly disclose a polymer fabric woven into the framework. Greenhalgh teaches co-braiding metal wires and polymer yarns to form a filter structure (Column 5 Lines 25-48). Therefore, it would have been

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obvious to a person having ordinary skill in the art at the time the invention was made to modify Douk's filter to include Greenhalgh's filter mesh. Such a modification would allow for control over the porosity of the filter. Also, modifying the pore size of the filter would have been obvious to a person having ordinary skill in the art to prevent particulates from escaping the filter. The Kusleika reference cited above notes that pore size should be between 20 and 1500 microns as desired (Column 4 Line 59).

**Claims 17 and 18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Douk et al. (2002/0151927) in view of Gillick et al. (US 6,383,206).

Douk discloses the invention substantially as claimed as stated above. Douk does not explicitly disclose the flexible members abutting to prevent blood flow. Gillick teaches the concept of a filter that prevents blood flow in one state (Column 4 Lines 5-8). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Douk's filter to include Gillick's state. Such a modification would prevent blood flow through the filter until the filter is properly placed. Also, modifying the pore size of the filter would have been obvious to a person having ordinary skill in the art to prevent particulates from escaping the filter. The Kusleika reference cited above notes that pore size should be between 20 and 1500 microns as desired (Column 4 Line 59).



### ***Response to Arguments***

Applicant's arguments filed 02/22/2008 have been fully considered but they are not persuasive.

The Applicant has argued regarding claim 1 that the core wire 42 of Douk is different than the claimed control cable. No reasoning was provided for this assertion. The argument appears to be based solely on the terminology used. The core wire and the control cable have the same function and are the same structure. Therefore, the argument is not persuasive. The Applicant has also argued that Douk does not present a filter with a convex surface relative to blood flow. The Examiner considers this language to be functional. Douk's filter is capable of being placed in a vessel such that a convex surface is presented to a flow of blood. Also, Douk's filter shape is considered convex because the surface bulges outward (see figure 1). The American Heritage Dictionary defines convex as having a surface or boundary that curves or *bulges* outward, as the exterior of a sphere. WordNet defines convex as curving or bulging outward. Also, look at the prior art of figure 4 in Douk, Greenhalgh figure 3, and Kusleika figure 1. The Examiner considers Douk's shape to be substantially convex..

The Applicant has also argued that Douk does not anticipate claim 9 because one might expect there to be differences between the tubular braided wire framework and the filter mesh. The claim language does not sufficiently differentiate the terms. The reference discloses the claimed subject matter. Also, the reference states that more than one material may be incorporated into the filter, thus providing the difference between the braid and the mesh.

Regarding the Applicant's arguments against the Examiner's rejection of claim 16, the device must necessarily have configurations between collapse and full expansion. Figure 18 describes the use of the filter. 102, 106, and 112 are clear indications that the filter collapses, expands, and then collapses again. This is standard for filters.

The Applicant has argued against the combination of Douk's embodiments to include a stop member to resist overexpansion. The Applicant has not pointed to any particular deficiency and has merely stated that the reference teaches to the dismantling of the mechanism. This is not persuasive. Also, the modification of the size of a device is generally considered well known to a person having ordinary skill. Making a device sized so that upon entry, exit, or use it does not cause unwanted damage to a vessel is a well-known reason for sizing the device accordingly. Making the device relatively small prior to deployment allows the device to navigate the vasculature with little or no damage to surrounding tissue.

The Applicant has argued that the claimed pore size is not obvious. Kusleika teaches that it is well known to make filters with the claimed pore size.

All other substantive arguments are based on the alleged deficiencies of Douk already addressed above.

### ***Conclusion***

This is a Continuation of applicant's earlier Application No. 10/748451. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731